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10/593,652	10/20/2006	Colin John Ingham	65959/58	2997	
1912 7590 0303/2010 AMSTER, ROTHSTEIN & EBENSTEIN LLP 90 PARK AVENUE			EXAM	EXAMINER	
			SCHUBERG, LAURA J		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/593,652 INGHAM, COLIN JOHN Office Action Summary Art Unit Examiner LAURA SCHUBERG 1657 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 07 December 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-49 and 54 is/are pending in the application. 4a) Of the above claim(s) 4.8.9.37.40-49 and 54 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-3,5-7,10-36,38-39 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftspreson's Patent Drawing Review (PTO-948)

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2) Immorrand Discosures Santement(s) (PTO/S50/06)

3) Hottes of Informati Patent Application

4) Interview Summary (PTO-413)

Paper No(s)/Mail Date.

5) Notice of Informati Patent Application

6) Other:

DETAILED ACTION

Applicant is requested to note that the Examiner for this application has changed.

Future correspondence should be directed to Laura Schuberg, Art Unit 1657, whose contact information can be found below.

Election/Restrictions

Applicant's election without traverse of Group 1a (claims 1-39) and species election (claims 1-3, 5-7, 10-36 and 38-39) in the replies filed on 5/1/2009 and 8/19/2009 is acknowledged.

Claims 1-49 and 54 are currently pending.

Claims 40-49 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 5/01/2009.

Claims 4, 8, 9, and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/19/2009.

Upon further consideration the species election for living organisms recited in claim 39 has been withdrawn as during examination the organisms listed were found to be art recognized equivalents for use with a solid porous support.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1-3, 5-7, 10-36 and 38-39 have been examined on their merits.

Information Disclosure Statement

The information disclosure statement filed 9/21/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein with regard to the DE 19841125 reference has not been considered. The rest of the references have been considered.

Specification

The use of the trademarks Anopore and Topas (pages 18 and 26) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 32 is objected to because of the following informalities: The term "2D" should be spelled out at its first appearance in the claims for purposes of clarity.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7, 10-36 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation wherein "said barriers are printed on the first surface of said porous support so that it is drawn into the porous support and as such, completely or in part comprised within the pores of the porous support" on lines 7-9. It is unclear if the term "it" refers to the barriers or the organism.

For examination purposes the term "it" is interpreted as referring to the barriers. Because claims 2-3, 5-7, 10-36 and 38-39 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

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Claim 10 recites the limitation "said permanent compound" in line 2. There is insufficient antecedent basis for this limitation in the claim as claim 1 which it is dependent upon does not recite a permanent compound.

For examination purposes claim 10 will be interpreted as dependent upon claim 2 which does recite a permanent compound.

Claim 39 recites the limitation "assuming that any ability to jump or fly is disabled if normally present" in lines 4-5.

The term "assuming" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

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USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "rubber", and the claim also recites "latex" which is the narrower statement of the range/limitation.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 13-19, 21-30, 34-36, 38 and 39 are rejected under 35
U.S.C. 102(b) as being anticipated by Van Damme et al (WO 03/102578-from IDS).

The claims are drawn to a device comprising a solid porous support having first and second surfaces, said first surface comprising an agent and/or condition that delineates behavioral and/or physical barriers for motile living organisms, and where behavioral said barriers adapted for sensing by the organisms and hence forcing the organisms to remain localized within a predefined region of the support without physically immobilizing the organisms, wherein the barriers are printed on the first

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surface of the support so that the barriers are drawn into the pores either partly or completely, therewith forming a three-dimensional compartmentalization of the porous support.

Dependent claims include the materials, components and properties that make up the porous support device.

Van Damme et al teach a solid porous flow-through support having a first and second surface (page 7 lines 23-24 and figures 3 and 10) that can be compartmentalized for microorganisms using a printing masking agent (page 29 lines 19-30). The mask is intended to compartmentalize the living array with a different analyte or cell-type applied to each compartment. The device is suitable for use with motile organisms such as nematodes and bacteria (page 5 lines 1-6). The living array allows the localization of effectors in controlled spots either printed directly or embedded in a matrix within the pores of the porous substrate (page 27, lines 25-30). A number of materials are suitable for use in forming the support and include metal oxides such as aluminum-oxide (page 7 lines 29-33). Wherein the porous support is non-invasive is interpreted as the support being incapable of transporting material through the solid support material as consistent with Applicant's disclosure (page 18 of the as filed specification) and is deemed to be provided by the use of the metal oxide solid support. Nutrients may be provided to the surface of the substrate and through the pores of the solid substrate (page 8 lines 32-33). Wherein the test compound (effector molecule) is a drug is taught (page 17 lines 17-25). Wherein an agent that delineates barriers is a repellent such as a protein is taught (page 17 lines 7-11). Wherein the surface of the

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substrate that is mixed with the agent is a permanent compound such as a polymer is taught (page 6 line 22-page 7 line 4 and page 29 lines 10-12). The barriers of the device appear flat in figures 3A, 4A and 10 and therefore the limitations of claim 5 are deemed to be met. Wherein a supply chamber is in contact with a second surface of the substrate and at least one compartment is provided with a liquid medium comprising at least one effector molecule is also taught (page 27 lines 13-23). Wherein at least one effector molecule is transported actively through the porous support, such as by pumping, is deemed to be an intended use limitation and since the solid porous support of the reference is in a format suitable for such an intended use (capable of having a media drawn over and through the substrate) this limitation is deemed to be met (page 28 lines 5-7).

Therefore the teaching of Van Damme et al anticipates Applicant's invention as claimed.

Claims 1-3, 5-7, 10-11, 13-19, 22-24, 27-32, 35-36 and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirk et al (US 2003/0022362-from IDS).

Kirk et al describe a device for testing behavior of motile microorganisms/cells in the presence of test substances including chemorepellents on a solid porous substrate with a first surface and a second surface (page 10 para 81-page 11 para 88, figures 1A-IC). A test device comprises a first well region (13a), a channel region (15a), a gel matrix (permanent compound) is poured onto the support (16) (page 3 para 20). The

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support member may also have a treatment on or embedded into its surface. This treatment may serve numerous functions, including facilitating the movement of cells being studied (page 8 para 67) and is interpreted as an agent that changes the texture of the surface as a lubricant. Wherein a supply chamber is in contact with a second surface of the substrate and contains at least one compartment and provides a liquid medium comprising at least one effector molecule with a gradient is taught (page 11 para 88). Wherein the gradient includes at least two effector molecules is taught as well (page 12 para 94). The application of a polymer material to the substrate combined with the agent forming the barriers is also taught (page 7 para 64). The device is taught to be suitable for use with motile forms of bacteria, fungi and motile gametes (page 10 para 83). Wherein at least one effector molecule is transported actively through the porous support, such as by pumping, is deemed to be an intended use limitation and since the solid porous support of the reference is in a format suitable for such an intended use (capable of having a media drawn over and through the substrate) this limitation is deemed to be met (figures 1A-1C). Wherein the porous support is non-invasive is interpreted as the support being incapable of transporting material through the solid support material as consistent with Applicant's disclosure (page 18 of the as filed specification) and is deemed to be provided by the use of the polymer solid support.

Therefore the teaching of Kirk et al anticipates Applicant's invention as claimed.

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Claims 1-3, 5-7, 13-20, 22-24, 27-31, 35-36, 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Holbrook (US 5,403,741).

Holbrook discloses a device for culturing or testing of motile organisms (specifically motile bacteria) comprising a solid carrier with channels (porous) with a first surface and a second surface to which a selective medium is adsorbed (column 6 lines 30-65 and column 15 lines 45-55). The selective medium which is applied to the carrier (made of a porous polymer filter-column 5 lines 25-35) together with a gelling agent is suitable for selective enrichment culture and indication of Salmonella and generates the migration of Salmonella through the carrier and therefore restricts the motile organism to predefined region of the support (column 6 lines 30-50). Wherein the support contains more than two zones of culture medium is taught (gradient)(column 5 lines 48-65) and a supply chamber that provides contact with a liquid medium and the second surface of the substrate (column 3 lines 1-5). Wherein the first surface is coated with a media gel that contains a poly-L-lysine compound is also taught (column 8 lines 35-65). The use of inhibitory agents (repellents-specifically salts) as agents of the device to provide barriers for the selected motile organisms is also taught (column 4 lines 25-36). The ability of the device to function as a flow-through solid porous support is taught (column 12 lines 10-20). Wherein the porous support is non-invasive is interpreted as the support being incapable of transporting material through the solid support material as consistent with Applicant's disclosure (page 18 of the as filed specification) and is deemed to be provided by the use of the polymer solid support.

Therefore the teaching of Holbrook anticipates Applicant's invention as claimed.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Damme (WO 03/102578-from IDS).

Claim 12 is dependent upon the device of claim 1 and further includes wherein the condition of the device is an energy source selected from a group.

Van Damme et al teach the device of claim 1 as described above and suggest as suitable the treatment of the device with an energy source such as thermal energy providing cold to influence the cells that are associated with the device (page 32 lines

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25-33). It appears from this disclosure that the treating of the device with an energy source is a suggested modification that can be applied to any of the embodiments.

Therefore one of ordinary skill in the art would have been motivated with a reasonable expectation of success to provide a device that had been treated with an energy source such as temperature in order to monitor the response of the selected organism to various temperatures as suggested by Van Damme et al.

Therefore the teaching of Van Damme et al renders obvious Applicant's invention as claimed.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kirk et al (US 2003/0022362-from IDS).

Claim 33 is drawn to the device of claim 29 and further includes wherein the number of compartments of the supply chamber and the number of predefined regions on the first surface are equal.

Kirk et al teach the device of claims 1, 27-29 as described above and suggest that by varying the configuration of the device the best channel region design for a given test may be obtained (page 7 para 63). It appears that providing the number of compartments and predefined regions to be of equal number to be of routine optimization and experimentation baring substantial evidence of unexpected results as these would be affected by the number and type of organism and test substances being analyzed.

Therefore one of ordinary skill in the art would have arrived at a device with the number of compartments and predefined regions to be of equal number by routine optimization and experimentation with a reasonable expectation of success baring substantial evidence of unexpected results.

Therefore the teaching of Kirk et al renders obvious Applicant's invention as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1993); *In re Goodman*, 11 F.3d 14046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3,73(b).

Claims 1-3, 5-7, 13-19, 21-30, 33-36, 38 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 7,419,778 in view of Van Damme et al (WO

03/102578-from IDS).

The claims of the patent '778 include the use of a flow-through solid porous substrate for the screening of responses of viruses, cells or cellular components and include many of the structural limitations of the presently claimed device such as the metallo-oxide substrate, predefined regions provided in the pores of the device and the printing of medium and test compounds onto the surface of the substrate as well as the

inclusion of drugs as test compounds.

The patent '778 claims do not specify the use of barriers in order to affect motile organisms, but this modification of a solid porous substrate as well as the use of suitable materials and modifications is suggested by Van Damme et al as described above.

Therefore the combined teachings of the claims of the patent '778 and Van

Damme et al render obvious Applicant's invention as claimed.

Claims 1-3, 5-7, 13-19, 21-30, 33-36, 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

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unpatentable over claims 11-17 and 21 of copending Application No. 10/593,793 in view of Van Damme et al (WO 03/102578-from IDS).

The claims of the copending application '793 include the use of a flow-through solid porous substrate for the screening of responses of viruses, cells or cellular components and include many of the structural limitations of the presently claimed device such as the metallo-oxide substrate, predefined regions provided in the pores of the device and the printing of medium and test compounds onto the surface of the substrate.

The copending application '793 claims do not specify the use of barriers in order to affect motile organisms, but this modification of a solid porous substrate as well as the use of suitable materials and modifications is suggested by Van Damme et al as described above.

Therefore the combined teachings of the claims of the copending application '793 and Van Damme et al render obvious Applicant's invention as claimed.

This is a <u>provisional</u> obviousness-type double patenting rejection.

Claims 1-3, 5-7, 13-19, 21-30, 33-36, 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-49, 51-53 of copending Application No. 11/662,397 in view of Van Damme et al (WO 03/102578-from IDS).

The claims of the copending application '397 include the use of a flow-through solid porous substrate for the screening of responses of viruses, cells or cellular components and include many of the structural limitations of the presently claimed device such as the metallo-oxide substrate, predefined regions provided in the pores of the device and the printing of medium and test compounds onto the surface of the substrate.

The copending application '397 claims do not specify the use of barriers in order to affect motile organisms, but this modification of a solid porous substrate as well as the use of suitable materials and modifications is suggested by Van Damme et al as described above.

Therefore the combined teachings of the claims of the copending application '397 and Van Damme et al render obvious Applicant's invention as claimed.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg Examiner Art Unit 1657

/Laura Schuberg/

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